

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2 din 29.11.2023

Solicitantul **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la**
(adresa)
Studentilor 6B, tel./fax: **079954795**, e-mail **oxivit.medical@gmail.com**,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a:

1. Intrumente medicale

- Se anexează următoarele acte:
- a) declarația de conformitate CE emisă de producător;
 - b) certificatul de conformitate CE;
 - c) Actul prin care producatorul isi desemneaza reprezentantul;

Data 29.11.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 8174 din 29.11.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Leonte Iuliane, Bioinginer
Semnătura persoanei responsabile	Leonte

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **SRL "Oxivit-med"**, cu sediul **mun. Chisinau, MD-2020, str-la Studentilor 6B,** (adresa)

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. Intrumente medicale

Sunt autentice și corespund realității.

Dmitrii Kojevnikov, Director
Numele, prenumele și funcția

Semnătura _____

Data 29.11.2023

We, **implantcast GmbH**, based in Germany, 21614 Buxtehude, Lüneburger Schanze 26,
(manufacturer) (address)

assign OXIVIT-MED SRL, based in Republic of Moldova, mun. Chisinau, MD-2020, str-la. Studentilor 6B,
(authorized representative) (address)

as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.


Vadim Lioubitski
Export Manager
C.I.S. countries
implantcast
implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Medical Device(s):	Instruments
Intended Use:	Reusable surgical instruments used for implantation an orthopaedic prosthesis.
REF Number(s):	REF-Numbers see Attachment I - I
Classification:	Class I (Council Directive 93/42/EEC, Annex IX, rule 6)
Standard(s) applied:	
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 10993-1	Instrumentation for use in association with non-active surgical implants - General requirements
EN ISO 16061	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN ISO 17664	Medical devices – Application of usability engineering to medical devices

We declare under our sole responsibility that the medical devices listed in the attachment(s) are in conformity with the essential requirements of Annex I of Council Directive 93/42/EEC and have undergone the conformity assessment procedure according to Annex VII of Council Directive 93/42/EEC.

Identification:



Buxtehude, 25.09.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

Attachment I

REF	Name	GMDN
79996715	MUTARS® RS ES container 2	44742
79996716	MUTARS® RS ES container 3	44742
79996721	MUTARS® RS broach container	44742
79996722	MUTARS® RS broach container 150mm	44742
79996723	MUTARS® RS broach container 200mm	44742
79996724	MUTARS® RS trial stem container	44742
79996725	MUTARS® RS trial stem cemented container*	44742
79996726	MUTARS® RS trial stem 120mm cemented container*	44742
79996727	MUTARS® RS trial stem container 150mm + 200mm	44742
79996731	MUTARS® RS trial stem container 250mm	44742
79997000	flexible reamer nitinol container	44742
79609999	ic-bipolar head container	44742
02201081	EcoFit® 2M container I	44742
02201082	EcoFit® 2M container II	44742
79990060	ic-cerclage container	44742
79995712	MUTARS® basic container	44742
79997701	MUTARS® trial container	44742
79997744	MUTARS® prox. femur RS trial container	44742
79997745	MUTARS® Prox. Femur trial container	44742
7999-5723	MUTARS® GenuX® femur container	44742
7999-5722	MUTARS® Genux® femur container	44742
7999-5734	MUTARS® proximal tibia container	44742
7999-5735	MUTARS® rigid drills container	44742
79995150	MUTARS® distal humerus container	44742
79995151	MUTARS® distal humerus left container	44742
79995152	MUTARS® distal humerus right container	44742
79995200	MUTARS® humerus container	44742
79995201	MUTARS® humerus invers container	44742
79995202	MUTARS® humerus trial container	44742
79995203	MUTARS® distal humerus 30mm for M6 long fit container	44742
79995204	MUTARS® distal humerus 30mm container	44742
79995205	MUTARS® proximal ulna container	44742
79995208	MUTARS® distal humerus 30mm for M6 container	44742
79995210	MUTARS® humerus container 14-16mm	44742

Attachment II

REF	Name	GMDN
79993831	AGILON® basic container	44742
79993832	AGILON® drill container	44742
79993833	AGILON® trial stem container	44742
79993834	AGILON® omarthrosis container	44742
79993816	AGILON® retractor container	44742
79993819	AGILON® CTA trial cap container	44742
79993822	AGILON® retentive inverse trial cap container	44742
79993836	AGILON® glenoid cemented sz. 2-4 container	44742
79993837	AGILON® glenoid cementless sz. 2-4 container	44742
79993838	AGILON® glenoid cementless inverse sz. 2-4 container	44742
79997043	EcoFit® easy lock Container	44742
02200036	EcoFit EPORE Container	44742

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

Effective date: 2020-12-01

Expiry date: 2024-05-27

Report No.: 7092FS12F
Process No.: QS – 7092
Certificate No.: 7092GB410201201A

Hamburg, 2020-12-01



MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

List of locations included in the scope of certificate

**Alter Postweg 10b
21614 Buxtehude
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
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Appendix of EC Certificate of Conformity

Process No.: QS – 7092

Certificate No.: 7092GB410201201A

List of products / product categories included in the scope of certificate

- **Primary endoprosthesis**
- **Tumor endoprosthesis**
- **Revision endoprosthesis**
- **Instruments (rasps, handles, reamer, drills, sawblades)**
- **Trial prostheses**
- **Metal augments**

– End of list –

This appendix is integral part of the above-referenced certificate.
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Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Tip Dispozitiv	Cod GMDN*
1	79997043	EcoFit® easy lock Container	EcoFit®	Instruments	44742
2	02200036	EcoFit EPORE Container	EcoFit®	Instruments	44742
3	79993831	AGILON® basic container	AGILON®	Instruments	44742
4	79993832	AGILON® drill container	AGILON®	Instruments	44742
5	79993833	AGILON® trial stem container	AGILON®	Instruments	44742
6	79993834	AGILON® omarthrosis container	AGILON®	Instruments	44742
7	79993816	AGILON® retractor container	AGILON®	Instruments	44742
8	79993819	AGILON® CTA trial cap container	AGILON®	Instruments	44742
9	79993822	AGILON® retentive inverse trial cap container	AGILON®	Instruments	44742
10	79993836	AGILON® glenoid cemented sz. 2-4 container	AGILON®	Instruments	44742
11	79993837	AGILON® glenoid cementless sz. 2-4 container	AGILON®	Instruments	44742
12	79993838	AGILON® glenoid cementless inverse sz. 2-4 container	AGILON®	Instruments	44742
13	79996715	MUTARS® RS ES container 2	MUTARS®	Instruments	44742
14	79996716	MUTARS® RS ES container 3	MUTARS®	Instruments	44742
15	79996721	MUTARS® RS broach container	MUTARS®	Instruments	44742
16	79996722	MUTARS® RS broach container 150mm	MUTARS®	Instruments	44742
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18	79996724	MUTARS® RS trial stem container	MUTARS®	Instruments	44742
19	79996725	MUTARS® RS trial stem cemented container*	MUTARS®	Instruments	44742
20	79996726	MUTARS® RS trial stem 120mm cemented container*	MUTARS®	Instruments	44742
21	79996727	MUTARS® RS trial stem container 150mm + 200mm	MUTARS®	Instruments	44742
22	79996731	MUTARS® RS trial stem container 250mm	MUTARS®	Instruments	44742
23	79997000	flexible reamer nitinol container		Instruments	44742
24	79609999	ic-bipolar head container		Instruments	44742
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30	79997744	MUTARS® prox. femur RS trial container	MUTARS®	Instruments	44742
31	79997745	MUTARS® Prox. Femur trial container	MUTARS®	Instruments	44742
32	7999-5723	MUTARS® GenuX® femur container	MUTARS®	Instruments	44742
33	7999-5722	MUTARS® Genux® femur container	MUTARS®	Instruments	44742
34	7999-5734	MUTARS® proximal tibia container	MUTARS®	Instruments	44742
35	7999-5735	MUTARS® rigid drills container	MUTARS®	Instruments	44742
36	79995150	MUTARS® distal humerus container	MUTARS®	Instruments	44742
37	79995151	MUTARS® distal humerus left container	MUTARS®	Instruments	44742
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43	79995204	MUTARS® distal humerus 30mm container	MUTARS®	Instruments	44742
44	79995205	MUTARS® proximal ulna container	MUTARS®	Instruments	44742
45	79995208	MUTARS® distal humerus 30mm for M6 container	MUTARS®	Instruments	44742
46	79995210	MUTARS® humerus container 14-16mm	MUTARS®	Instruments	44742